OCT 17 2005

510(k) Summary
Codman Integrated Irrigation Tubing and Bipolar Cord Set

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

K052449

Contact Person

Joan Q. Bartle, RAC
Sr. Regulatory Affairs Specialist
Telephone Number: (508) 828-2840
Fax Number: (508) 828-2777

Name of Device

Proprietary Name:	Codman Integrated Irrigation Tubing and Bipolar Cord Set
Common Name:	Irrigation Tubing and Bipolar Cord
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories

Device Classification

Electrosurgical Cutting and Coagulation Device and Accessories are Class II devices per 21 CFR § 878.4400 (79 GEI).

Statement of Substantial Equivalence

Codman Integrated Irrigation Tubing and Bipolar Cord Sets are substantially equivalent to the Codman/Malis Integrated Irrigation Tubing and Bipolar Cord Set based on the device's similarity to the predicate device in intended use, materials, design, and principles of operation.

Indications for Use

The Codman Integrated Irrigation Tubing and Bipolar Cord Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation.

They are intended to for use with the Codman/Malis CMC®-II and the Codman/Malis CMC® III I.E.C. Irrigation Modules and the Codman/Malis Bipolar Coagulators.

K052449

Page 2 of (2)

Physical Description

The Codman Integrated Irrigation Tubing and Bipolar Cord Set is designed to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation. A co-extrusion process integrates a disposable bipolar cord with an irrigation tubing set. This integrated set allows for one unit instead of two units and helps to keep the bipolar electrosurgery organized.

Device Testing

Substantial equivalence for this device is based upon comparison to predicate device characteristics and performance testing. Device qualification criteria meet or exceed the minimum qualification criteria for the predicate device. Tests meet the performance criteria set forth by the Association for the Advancement of Medical Instrumentation (AAMI) in the ANSI/AAMI HF18: 2001: Electrosurgical devices § 4.2.5.1-3, 5.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

Codman & Shurtleff, Inc.
c/o Patricia L. Murphy
Third Party Officials Reviewer
KEMA Quality B.V.
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K052449
Trade/Device Name: Codman Integrated Irrigation Tubing and Bipolar Cord Set
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 7, 2005
Received: October 11, 2005

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052449

Device Name: **Codman Integrated Irrigation Tubing and Bipolar Cord Set**

Indications For Use:

The Codman Integrated Irrigation Tubing and Bipolar Cord Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation.

They are intended for use with the Codman/Malis CMC®-II and the Codman/Malis CMC® III I.E.C. Irrigation Modules and the Codman/Malis Bipolar Coagulators.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052449